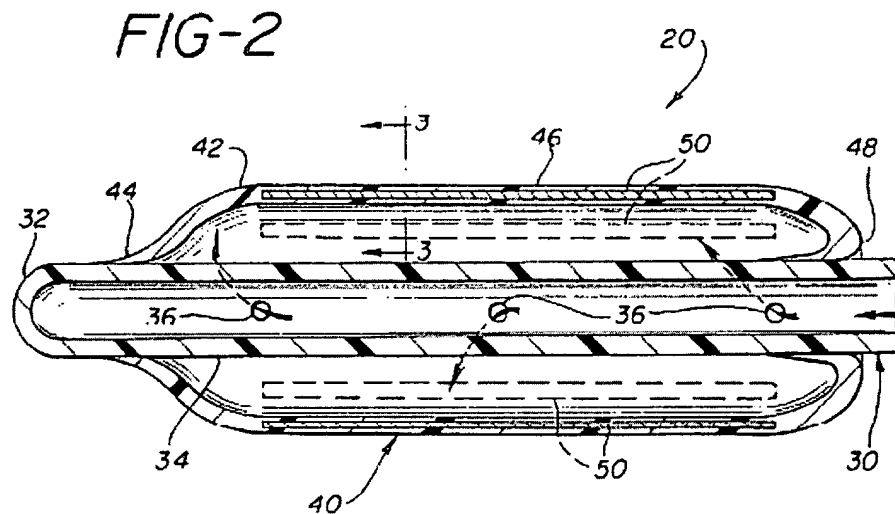


As shown in Fig. 2 of Grayzel '629, which is reproduced below, Grayzel describes a balloon catheter 20 including a balloon 30 having a stiffening member 50 embedded in skin 42 of balloon 40. *See, e.g.*, Col. 4, lines 20-24 and 53-57. Grayzel notes that the stiffening member can alternatively be disposed on the outer surface of his balloon. *See, e.g.*, Col. 5, lines 13-17. According to Grayzel, the use of the stiffening members can amplify that force that can be exerted by the balloon on surface irregularities. *See, e.g.*, Col. 6, lines 42-45.



Grayzel '680 discloses a balloon catheter having a balloon with stiffening members that aid in uniform expansion of the balloon at a target site in a lumen in the human body. *See, e.g.*, Col. 3, lines 25-28. Referring to Grayzel's Fig. 5B, which is reproduced below, Grayzel '680 describes a device 110 including a balloon 112 with embedded stiffening members 114. *See, e.g.*, Col. 9, lines 27-30. Grayzel notes that stiffening members 114 can alternatively be positioned on the outside of the balloon. *See, e.g.*, Col. 9, lines 17-19.

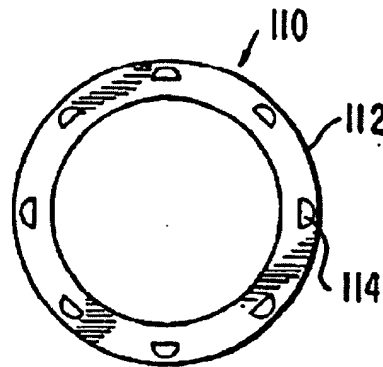


FIG. 5B

The Examiner contended that it would have been obvious to a person of ordinary skill in the art to modify Vigil's balloon in view of Grayzel '629 by encapsulating Grayzel's stiffening members within Vigil's balloon material to support Vigil's cutting elements and exert a greater force to assist anchoring Vigil's cutting elements into a treated surface. The Examiner further contended that it would have been obvious to modify the resulting device to have reinforcing members as disclosed in Grayzel '680 to provide more flexibility to the balloon and provide means for locating the device within a body lumen.

However, a person of ordinary skill in the art would not have been motivated to modify Vigil's balloon to include the stiffening members of Grayzel '629 in a manner such that Vigil's cutting elements would be located over the encapsulated stiffening members. According to Grayzel, the stiffening members described in Grayzel '629 could be disposed on the outer surface of his balloon. Therefore, a person of ordinary skill in the art would have recognized that Vigil's cutting elements, which are similarly described as being mounted on the outer surface of the balloon, would provide a function similar to that of Grayzel's stiffening members. As a result, a person of ordinary skill in the art would likely have been discouraged from combining Vigil and Grayzel '629 in the manner suggested by the Examiner. Because both Vigil's cutting elements and Grayzel's stiffening members would function to stiffen the regions of the balloon in/on which they are positioned, disposing Vigil's cutting elements over Grayzel's stiffening

members would at the very least be redundant and could likely result in an overly stiffened region of the balloon.

For similar reasons, a person of ordinary skill in the art would not have been motivated to modify Vigil's balloon to include the stiffening members of Grayzel '680 in a manner such that Vigil's cutting elements would be located over the encapsulated stiffening members. According to Grayzel, the stiffening members described in Grayzel '680 could be positioned on the outside of the balloon. Therefore, a person of ordinary skill in the art would have recognized that Vigil's cutting elements, which are similarly described as being mounted on the outer surface of the balloon, would provide a function similar to that of Grayzel's stiffening members. Thus, a person of ordinary skill in the art would likely have been discouraged from modifying Vigil's balloon in a manner such that Vigil's cutting elements would be located over the encapsulated stiffening members. Such an arrangement would at the very least be redundant and could likely result in an overly stiffened region of the balloon.

Vigil, Grayzel '629, and Grayzel '680, taken alone and in combination, fail to disclose or suggest each of the above-noted elements of Applicants' claims. As discussed above, a person of ordinary skill in the art would not have been motivated to combine these references in the manner suggested by the Examiner. Therefore, Applicants request reconsideration and withdrawal of the rejection of Applicants' claims.

Claims 1-4, 6-18, 20-34, 36, 43 and 73-81 were also rejected under 35 U.S.C. § 103(a) as being unpatentable over Grayzel '629 in view of Barath (U.S. Patent No. 5,196,024). Applicants' claims, as discussed above, cover medical devices including a balloon having a first material and a second material (or striped portion) encapsulated by the first material and a cutting element carried by (or attached to) the balloon over the second material (or striped portion). Grayzel '629 and Barath, taken alone and in combination, fail to disclose or suggest each of the above-noted elements of Applicants' claims.

As discussed above, Grayzel describes a balloon catheter 20 including a balloon 30 having a stiffening member 50 embedded in skin 42 of balloon 40. Grayzel notes that the stiffening member can alternatively be disposed on the outer surface of his balloon.

Barath discloses a balloon catheter with cutting elements, and, according to Barath, the balloon catheter can be used to make longitudinal surgical cuts in a vessel wall. *See, e.g.*, Col. 1, lines 4-12.

The Examiner contended in the office action that it would have been obvious to a person of ordinary skill in the art to dispose Barath's cutting elements on the surface of Grayzel's balloon in order to further treat a stenosis. The Examiner further contended that it would have been obvious to place Barath's cutting elements at the area of Grayzel's balloon including reinforcing members in order to optimize the placement of the blades into the stenosis.

However, a person of ordinary skill in the art would not have been motivated to modify Grayzel's balloon to include Barath's cutting elements in a manner such that Barath's cutting elements would be located over the encapsulated stiffening members of Grayzel's balloon. According to Grayzel, the stiffening members described in Grayzel '629 could be disposed on the outer surface of the balloon. Therefore, a person of ordinary skill in the art would have recognized that Barath's cutting elements, which are similarly described as being mounted on the outer surface of the balloon, would provide a function similar to that of Grayzel's stiffening members. As a result, a person of ordinary skill in the art would likely have been discouraged from making such a combination. Because both Barath's cutting elements and Grayzel's stiffening members would function to stiffen the regions of the balloon in/on which they are positioned, disposing Barath's cutting elements over Grayzel's stiffening member would at the very least be redundant and could likely result in an overly stiffened region of the balloon.

Grayzel '629 and Barath, taken alone and in combination, fail to disclose or suggest each of the above-noted elements of Applicants' claims. A person of ordinary skill in the art would not have been motivated to combine Grayzel '629 and Barath in the manner suggested by the Examiner. Therefore, Applicants request reconsideration and withdrawal of the rejection of Applicants' claims.

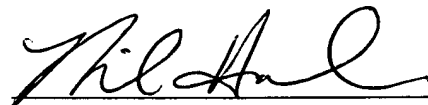
Enclosed is a Enter \$300 amount check for excess claim fees and a \$120 check for the Petition for Extension of Time fee. Please apply any other charges or credits to deposit account 06-1050.

Applicant : Lixiao Wang et al.
Serial No. : 10/083,926
Filed : February 27, 2002
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Attorney's Docket No.: 10527-395001 / 02-026

Respectfully submitted,

Date: September 28, 2006

A handwritten signature in black ink, appearing to read "Michael R. Hamlin", written over a horizontal line.

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